

Appl. Serial No. 10/817,335  
Response dated September 6, 2007  
Response to Office Action dated March 6, 2007

### **III. Remarks**

Claims 1, 2, 4, 5, 7-12 and 39-52 are pending. Claim 39 has been amended to clarify the particle size units and to correct an inadvertent term omission. Reconsideration of this application, in view of the amendments made and arguments presented herein, is respectfully requested. No new matter has been added by virtue of the present amendments.

#### **A. Examiner's Comments Regarding Information Disclosure Statement**

In the Office Action mailed March 6, 2007, the Examiner stated that the reference "Machines Collette High Shear Mixer Granulator Promotional Literature (date unknown)" listed in the Information Disclosure Statement filed April 2, 2004 fails to comply with 37 C.F.R. § 1.98(a)(2), which requires a legible copy of the reference. In response, Applicants submit herewith a replacement copy of this reference and respectfully request that it be considered by the Examiner and made of record.

#### **B. Specification**

In the Office Action, the Examiner required the specification to be amended to include cross reference to related application 10/266,518 filed October 8, 2002, now U.S. Patent No. 6,746,693. In response, Applicants respectfully submit that this amendment to the specification was submitted in Applicants' Preliminary Amendment dated April 2, 2004 and entered according to the electronic image file wrapper in connection with the present application in "public pair", accessible through the United States Patent and Trademark Office's website. However, to satisfy the Examiner's request, Applicants have submitted herewith another amendment to the specification as required by the Examiner.

Appl. Serial No. 10/817,335  
Response dated September 6, 2007  
Response to Office Action dated March 6, 2007

**C. Obviousness-type Double Patenting Rejection**

In the Office Action, the Examiner rejected claims 1, 2, 4-5, 7-12 and 51-52 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 21 and 23-27 of U.S. Patent No. 6,103,219.

The Examiner also rejected claims 39-42 and 46-50 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 19, 20, 24, 30, 32 and 33 of U.S. Patent No. 6,746,693 in view of claims 25-27 of U.S. Patent No. 6,103,219.

In response, Applicants submit that they will consider filing a Terminal Disclaimer in view of these rejections in the event that the claims are otherwise found allowable.

**D. 35 U.S.C. §103 Rejections**

In the Office Action, the Examiner also rejected claims 1, 2, 4, 5, 7-12 and 39-52 under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 4,605,666 to Schmidt et al. ("Schmidt"). The Examiner stated that "Schmidt teaches a 'process for preparing a powder ... which is directly compressible into a tablet prepared by spray drying (a) an aqueous slurry of water soluble vitamin and a binder; (b) ... an adsorbent; and (c) a lubricant' (Abstract)." The Examiner also stated "[i]t is taught that the powders are directly compressible into tablets ...". The Examiner further stated that "[i]n example 1 an aqueous slurry of ascorbic acid, microcrystalline cellulose and water is spray dried and silicon dioxide is added (Col. 3, lines 29-49) ... [and that] [t]he adsorbent is silicon dioxide (Col. 7, lines 14-15) and the binder is microcrystalline cellulose (Col. 8, lines 4-5)."

The Examiner then concluded that “a person having ordinary skill in the art at the time the invention was made could have used the aqueous slurry taught by Schmidt and included the adsorbent silicon dioxide into the slurry prior to spray drying instead of adding it to the spray dried mixture. This would have been part of the routine experimentation strategy to optimize the compressibility of the final tablet.” The Examiner also stated that “[p]rior to tableting, the excipients and active ingredient are mixed; therefore a ‘plurality of agglomerated particles’ would be achieved.” The Examiner also concluded that “[r]egarding instant claim 39, a person having ordinary skill in the art could use the teaching of Schmidt and prepare separate aqueous slurries of microcrystalline cellulose and silicon dioxide prior to spray drying as part of routine experimentation in order to determine which resultant excipient offered the best compressibility.”

The Examiner’s rejection is respectfully traversed. Independent claim 1 of the present invention recites, in pertinent part, a method for preparing a tablet comprising... “forming an aqueous slurry containing a mixture of microcrystalline cellulose in the form of a wet cake and silicon dioxide ... ; drying said slurry to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with said silicon dioxide ...[and] mixing an active agent with said excipient ...”

Independent claim 39 of the present invention (as amended herein) recites, in pertinent part, “(a) forming an aqueous slurry of microcrystalline cellulose in the form of wet cake; (b) forming an aqueous slurry of silicon dioxide having a particle size of from about 1 nm to about 100  $\mu$ m; (c) separately introducing said microcrystalline cellulose slurry and said silicon dioxide slurry separately into a drying apparatus for combination therein, to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with said silicon dioxide ... [and] (d) mixing an active ingredient with said excipient ...”

The Schmidt reference describes a process for preparing a powder containing a water-soluble vitamin which is directly compressible into a tablet, the process including preparing an aqueous slurry containing an active agent, e.g., a water-soluble vitamin, and a binder, e.g., microcrystalline cellulose; the active agent /microcrystalline cellulose slurry is then introduced into a spray-dryer. The adsorbent, e.g., silicon dioxide, is added into the drying chamber at a point of negative pressure (See: Examples 1-5 cols. 3-5). Nowhere does the Schmidt reference teach or suggest “forming an aqueous slurry containing a mixture of microcrystalline cellulose in the form of a wet cake and silicon dioxide ... ; drying said slurry to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with said silicon dioxide as recited in independent claim 1 of the present invention. Nor does the Schmidt reference teach or suggest “(a) forming an aqueous slurry of microcrystalline cellulose in the form of wet cake; (b) forming an aqueous slurry of silicon dioxide having a particle size of from about 1 nm to about 100  $\mu$ m; (c) separately introducing said microcrystalline cellulose slurry and said silicon dioxide slurry separately into a drying apparatus for combination therein, to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with said silicon dioxide as recited in independent claim 39 of the present invention.

Applicants respectfully submit that the Examiner is relying on impermissible hindsight by stating that a person having ordinary skill in the art at the time the invention was made could have used the aqueous slurry taught by Schmidt and (i) “...included the adsorbent silicon dioxide into the slurry prior to spray drying instead of adding it to the spray dried mixture”; or (ii) “... prepare[d] separate aqueous slurries of microcrystalline cellulose and silicon dioxide prior to spray drying as part of routine experimentation in order to determine which resultant excipient offered the best compressibility.” Applicants respectfully submit that there is no basis provided in the Schmidt reference for one of skill in the art to utilize the silicon dioxide as an adsorbent

Appl. Serial No. 10/817,335  
Response dated September 6, 2007  
Response to Office Action dated March 6, 2007

that is separately added within the drying chamber at a point of negative pressure. Whereas the aqueous slurries claimed in the present invention are not added to the spray-dryer at a point of negative pressure.

However, assuming *arguendo*, that the Schmidt reference provided a basis for a person having ordinary skill in the art at the time of the invention to add silicon dioxide to the slurry of the Schmidt reference prior to spray-drying, they would still not arrive at the present invention which requires the formation of a "pre-manufactured" excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with the silicon dioxide, prior to the addition of an active agent, which mixture is then compressed into a tablet. Instead, they would obtain a mixture of the active agent, microcrystalline cellulose and silicon dioxide.

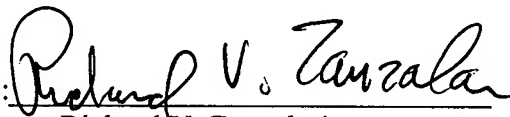
Accordingly, independent claim 1 and the claims that depend there from and independent claim 39 and the claims that depend there from are not obvious under 35 U.S.C. § 103(a) in view of the Schmidt reference. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

Appl. Serial No. 10/817,335  
Response dated September 6, 2007  
Response to Office Action dated March 6, 2007

**IV. Conclusion**

In view of the amendments made and arguments presented, it is respectfully submitted that the present application is now in condition for allowance. An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of the application. A request for a three-month extension of time to reply to the Office Action along with the requisite fee is enclosed.

Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By:   
Richard V. Zanzalari  
Reg. No. 49,032

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> floor  
New York, New York 10018  
(212) 736-1940